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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, TAKEDA PHARMACEUTICALS AMERICA, INC., and ETHYPHARM, S.A.,	:	Civil Action No. 3:10-CV-01723-JAP-TJB
Plaintiffs and Counterclaim-Defendants, v.	:	PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANTS' MOTION FOR RECONSIDERATION OF ORDER DENYING IN PART LEAVE TO AMEND PRELIMINARY INVALIDITY AND NON-INFRINGEMENT CONTENTIONS
ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED,	:	
Defendants and Counterclaim-Plaintiffs.	:	

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PRELIMINARY STATEMENT

"[A] motion for reconsideration should not provide the parties with an opportunity for a second bite at the apple." *Church & Dwight Co. v. Abbott Labs.*, 545 F. Supp. 2d 447, 450 (D.N.J. 2008) (citation omitted). With their motion ("Motion"), Defendants Zydus Pharmaceuticals USA Inc. and Cadila Healthcare Limited (together, "Zydus" or "Defendants") try to do just that by (1) identifying an alleged "intervening change of controlling law" that neither changes the law nor is relevant to the challenged decision; (2) raising a "manifest error of fact" where there is none and when there are separate grounds independently justifying the Court's decision; and (3) rehashing arguments that this Court has already considered and rejected. Zydus' Motion should be denied.

On June 11, 2012, in a carefully reasoned, 33-page decision, this Court granted-in-part and denied-in-part Defendants' motion for leave to amend its non-infringement and invalidity contentions. Doc. 191 ("Opinion") & 192 ("Order"). Zydus now seeks reconsideration of the Court's denial of its proposed amendments pertaining to (1) invalidity of U.S. Patent No. 5,464,632 ("the '632 patent") based on impermissible broadening during reexamination and (2) non-infringement of U.S. Patent Nos. 6,328,994 ("the '994 patent"), 7,431,942 ("the '942 patent"), 7,875,292 ("the '292 patent") due to average particle diameter. On both issues, the Court found Defendants' proposed amendments untimely and rejected arguments that Zydus repeats in this Motion.

Ultimately, Zydus' Motion is an attempt to get a second bite of the apple and should be denied; Zydus fails to establish any legal or factual justification for modifying the Court's Order.

ARGUMENT

I. The Legal Standard for Motions for Reconsideration

A motion for reconsideration is an "extraordinary remedy" that should be "granted only sparingly." *AstraZeneca Pharmas. LP v. Handa Pharmas, LLC*, No. 08-3773 (JAP), 2011 WL 601612, at *2 (D.N.J. Feb. 17, 2011) (Pisano, J.); *Church & Dwight*, 545 F. Supp. 2d at 449. Because such motions "place[] a heavy burden on the movant," they are "only appropriate when one of the following three grounds for relief is established: '(1) an intervening change in the controlling law has occurred; (2) evidence not previously available has become available; or (3) it is necessary to correct a clear error of law or prevent manifest injustice.'" *AstraZeneca*, 2011 WL 601612 at *2 (citation omitted); *see also Howard Hess Dental Labs. Inc. v. Denstply Int'l, Inc.*, 602 F.3d 237, 251 (3d Cir. 2010).

To justify reconsideration, a party "'must show more than a disagreement with the Court's decision.'" *FMC Corp. v. Guthery*, No. 07-5409 (JAP), 2009 WL 2488148, at *1 (D.N.J. Aug. 11, 2009) (Pisano, J.) (quoting *G-69 v. Degnan*, 748 F. Supp. 274, 275 (D.N.J. 1990)). It is thus "improper" on a motion for reconsideration to "ask the Court to rethink what it had already thought through—rightly or wrongly." *FMC Corp.*, 2009 WL 2488148, at *3 (quoting *Oritani Savings & Loan Ass'n v. Fidelity & Deposit Co.*, 744 F. Supp. 1311, 1314 (D.N.J. 1990)). "Instead, the moving party is obligated to point out controlling facts or dispositive case law that the Court necessarily overlooked in rendering its decision." *Ciba-Geigy Corp. v. Alza Corp.*, No. 91-5286, 1993 WL 90412, at *1 (D.N.J. Mar. 25, 1993); *Altay v. Tagayun*, No. 06-2330 (JLL), 2006 WL 3827426, at *1 (D.N.J. Dec. 28, 2006). Defendants do not meet this standard. Accordingly, their Motion should be denied.

II. Neither an Intervening Change in Controlling Law Nor a Manifest Error of Fact Justifies Reconsideration of Defendants' Impermissible Broadening Argument

A. *In re Youman* Is Not Controlling Law

Zydis argues that *In re Youman*, 679 F.3d 1335 (Fed. Cir. 2012) is an intervening "sea change" in controlling law that justifies reconsideration. Defendant's Brief ("Def. Br.") at 6-10. Zydis is wrong.

As an initial matter, *In re Youman* is not controlling law because this Court denied Zydis' proposed amendment (that the '632 patent was impermissibly broadened during reexamination) based on timeliness considerations. *See* Opinion at 21 ("The Court finds that Zydis was not sufficiently diligent in seeking to amend its Contentions on this theory."). This Court did not have to address the underlying merits of Defendants' proposed amendment because that amendment was simply too late. In short, because *In re Youman* is irrelevant to this Court's determination, it does not support reconsideration. *See D & D Assocs., Inc. v. Bd. of Educ. of N. Plainfield*, No. 03-1026 (MLC), 2009 WL 904054, at *2 (D.N.J. Mar. 31, 2009) ("[A] decision that is not controlling precedent is not an intervening change in the controlling law for purposes of a motion for reconsideration . . .") (citations omitted).

Moreover, *In re Youman* is not controlling law because it expressly concerns reissued patents and not reexamined patents, such as the '632 patent-in-suit. *In re Youman*, 679 F.3d at 1342 ("Prior to evaluating the Board's rejection based on the recapture rule, it is important to understand the statutory source from which the judicial recapture rule stems—the reissue statute."). In fact, *In re Youman* does not even mention patent reexaminations, and there is no indication whatsoever that the Federal Circuit intends that *In re Youman* will apply to reexamination proceedings. Thus, there is no basis to conclude that *In re Youman* even applies to Defendants' rejected amendment.

Further, Zydus' characterization of *In re Youman* as a "sea change" in law is baseless. Def. Br. at 6-10. As the case itself makes clear, it did not change the law even with respect to impermissible broadening of reissued patents, which was the issue addressed in the case. The Federal Circuit expressly stated that its holding—that material narrowing should be determined relative to the original claim as filed rather than the patented claim as issued—was "consistent both with case law and the purposes underlying the reissue statute." *In re Youman*, 679 F.3d at 1345-46 & n.4 (collecting cases). The Federal Circuit also remanded the case so that the PTO Board could "properly apply the recapture rule analysis, as articulated in this opinion and in *Mostafazadeh* [a Federal Circuit case from 2011]." *Id.* at 1348 (emphasis added). At most, *In re Youman* clarified what even the dissent conceded was a "complicated" body of law.¹ That is not sufficient to justify reconsideration.²

Had Defendants truly thought *In re Youman* was an intervening "sea change" of controlling law, it was incumbent upon them to raise it promptly to the Court's attention. Instead, Defendants waited five weeks to raise the issue. Faced with such facts, courts deny reconsideration. See *Amersham Biosciences*, 2006 WL 3485918 at *2 n.2 (denying motion for

¹ If anything, *In re Youman* has made it easier for patentees to broaden their claims during reissue while avoiding the recapture rule. *Id.* at 1344-48. The Federal Circuit rejected an essentially *per se* rule against reissued claims of intermediate scope and held that "if the patentee modifies the added limitation such that it is broader than the patented claim yet still materially narrows relative to the original claim, the recapture rule does not bar reissue." *Id.* at 1347. As such, *In re Youman* cannot possibly strengthen Defendants' argument so as to justify reconsideration and leave to amend.

² *N. Plainfield Bd. of Educ. v. Zurich Am. Ins. Co.*, No. 05-4398 (MLC), 2011 WL 1044239, at *2 (D.N.J. Mar. 17, 2011) ("[E]ntry of a binding precedent, which clarifies—rather than alters the existing legal regime—cannot qualify as an intervening change in the law.") (internal quotation, modification, and citation omitted), *aff'd*, Nos. 11-2323, 11-1961, 2012 WL 1788132 (3d Cir. May 17, 2012); *Amersham Biosci. Corp. v. PerkinElmer, Inc.*, No. 03-4901 (JLL), 2006 WL 3485918, at *2 (D.N.J. Nov. 30, 2006) ("Having reviewed the *Inpro* decision, the Court finds that although it is certainly a 'new Federal Circuit' case, it does not constitute a change in controlling law, and thus does not warrant this Court's reconsideration.").

reconsideration: "The Court further notes that Defendant had every opportunity to bring this case to the Court's attention prior to the Court's decision . . . Defendant [had] almost a full two weeks to notify the Court of any purported significant development in caselaw."). This Court should do the same.

B. There Is No Manifest Error of Fact Because the Record Supports the Court's Decision

Defendants next argue that reconsideration is appropriate because the Court "made a manifest error of fact in basing its decision on the erroneous belief that the Court previously adopted Zydus' construction of the phrase 'to achieve in less than 60 seconds a suspension easy to swallow.'" Def. Br. at 3, 10-11. Defendants' argument is a red herring.

As an initial matter, the underlying claim construction of "to achieve in less than 60 seconds a suspension easy to swallow" is completely irrelevant to Defendants' argument that claim 1 of the '632 patent was impermissibly broadened during reexamination. That argument focuses on where the tablet disintegrates, not the time within which it must do so. *See Doc. 140-9 at 7* ("the original claim . . . referenced the time needed for the swallowed tablet to fully disintegrate after swallowing, rather than disintegration in the mouth as the claim presently reads.") (second emphasis added). In sharp contrast, the parties' claim construction dispute focused on the timing of disintegration (*e.g.*, "mean time" versus "absolute time"). *See Doc. 113 at 17*. Zydus has not, and cannot, explain how claim construction as to timing can support a finding of good cause to add an impermissible broadening contention as to where disintegration occurs. Indeed, the Court has already rejected Defendants' argument that the *Markman* Order somehow justifies its proposed amendment. Opinion at 21.³

³ In relevant part, the Order reads: "Zydus contends that its January 2012 expert report and the Court's claim construction ruling prompted this proposed change; however, Zydus explains that

In any event, Zydus is wrong; the Court's denial of leave to amend was not based on a clear or manifest error of fact. Under New Jersey law, "[a] decision suffers from 'clear error' only if the record cannot support the findings that led to that ruling." *Leja v. Schmidt Mfg., Inc.*, 743 F. Supp. 2d 444, 456 (D.N.J. 2010) (denying reconsideration). "Thus, a party must do more than allege that portions of a ruling were erroneous in order to obtain reconsideration of that ruling; it must demonstrate that (1) the holdings on which it bases its request were without support in the record, or (2) would result in 'manifest injustice' if not addressed." *Id.* Defendants do not and cannot make such a showing.

To the contrary, the record amply supports the Court's determination that "the Court adopted Zydus' proposed construction by determining that no construction of the term . . . was necessary." Opinion at 22. In the Revised Joint Claim Construction and Prehearing Statement, for example, Defendants stated that "[t]he claim limitation should be considered to have its plain meaning and does not require construction." Doc. 94, Rev'd Ex. A, at 13; *see also* Doc. 69-2, Ex. 5, p. 13.⁴ That document, which was submitted to the Court after the *Markman* hearing, reflects the parties' final claim construction positions.

Moreover, as Defendants concede, the Court denied leave to amend on a number of grounds – not limited to the particular ground that Zydus presently asserts is a "[m]anifest [e]rror of [f]act." Def. Br. at 10. The Court repeatedly stressed that Zydus' motion was untimely in many respects:

- "There is nothing before the Court to indicate that this newly proposed argument could not have been raised at that time [during claim construction] as well." Opinion at 21.

its expert's opinion on this issue was based, in part, on the original claim recitation: information which has been available to Zydus since the inception of this lawsuit."

⁴ Defendants are thus wrong to claim that they "did consistently argue that the term required construction." Def. Br. at 11.

- The proposed amendment is "based, in part, on the original claim recitation: information which has been available to Zydus since the inception of this lawsuit." *Id.*
- "[T]he Court finds that Takeda was not given sufficient notice of this theory as asserted by Zydus and, thus, Takeda would be prejudiced if amendment to include this argument were permitted." *Id.* at 22.

Nowhere in their brief do Defendants' rebut, let alone contest, any of these separate findings that undergird the Court's denial of leave to amend. Thus, these findings provide an independent ground for denying reconsideration and reaffirming the denial of leave to amend.

III. The Court Has Already Considered and Rejected Defendants' Arguments Seeking Amendment of Non-Infringement Contentions Based on Average Particle Size

Defendants only rehash previously rejected arguments in seeking reconsideration of the Court's denial of their proposed amendment as to average particle size. *Altay*, 2006 WL 3827426 at *1 ("The motion may not be used to re-litigate old matters."). Once again, Defendants argue that they seek only "to correct" an "error" by replacing their long-held non-infringement position with newly-performed expert calculations and that, absent amendment, they will suffer prejudice. *Compare* Def. Br. at 12-14 *with* Doc. 140-9 at 10-12. As each of these arguments was previously considered and rejected by the Court, they do not now justify reconsideration. *See* Opinion at 5-6, 23-24; Doc. 130 (Reconsideration Order) at 2 ("Defendants do little more than argue that the Court erred in its [ruling], and they repeat a number of arguments that had earlier been presented to and evaluated by the Court. This simply is not sufficient.").⁵

⁵ See also, e.g., *AstraZeneca*, 2011 WL 601612 at *2 (denying reconsideration where defendant "offer[ed] nothing more than recapitulation of the cases and arguments considered by the Court before rendering its original decision.") (internal quotation, modification, and citation omitted); *Schering Corp. v. Mylan Pharms., Inc.*, No. 09-6383, 2011 WL 3328940, at *1 (D.N.J. Aug. 1, 2011) (denying reconsideration where defendant "simply resubmit[ed] arguments that were already presented to this Court").

Notably, Defendants still do not explain "how this significant error [as to average particle size] occurred or . . . why this mistake could not have been discovered sooner." Opinion at 24. Thus, even if reconsideration were appropriate (which it is not), leave to amend would still not be warranted. Opinion at 24. Because good cause has not been shown, Defendants' motion should be denied.

CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that the Court deny Defendants' Motion for Reconsideration and reaffirm its Order granting-in-part and denying-in-part Defendants' motion for leave to amend its non-infringement and invalidity contentions.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the foregoing PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANTS' MOTION FOR RECONSIDERATION OF ORDER DENYING IN PART LEAVE TO AMEND PRELIMINARY INVALIDITY AND NON-INFRINGEMENT CONTENTIONS was caused to be served on July 2, 2012 via email and the ECF system upon all counsel of record.

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